

MODULE 3

FINANCIAL SUSTAINABILITY **THE LEARNING NETWORKS GUIDE: BUILDING A** **LEARNING HEALTHCARE SYSTEM NETWORK**

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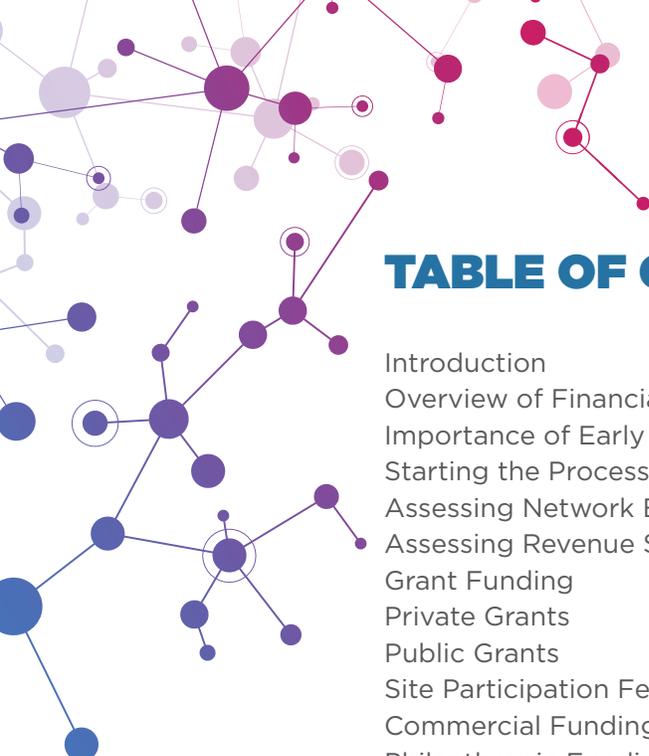
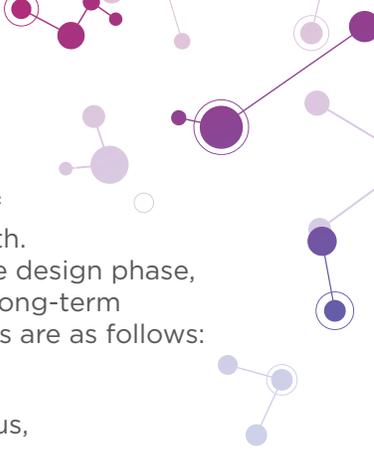


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As networks move through the design phase and into subsequent growth phases, more infrastructure (lighting, desks, etc.) is required to run the day-to-day operations of a network. Gaps in funding result in significant operational disruption and impede growth. While securing initial start-up funding for a learning health system is a critical step in the design phase, thinking about future funding sources is equally critical to maximizing the likelihood of long-term success resulting in the greatest impact on improving outcomes. The key reasons for this are as follows:

- Success is expensive—it requires continued growth and development of a network;
- Longer-term funding enables the stability to engage in longer-term planning and thus, a broader vision;
- By establishing a sustainable funding plan, leaders maximize their time by focusing on network research and improvement efforts with minimal distraction from the need to chase short-term funding opportunities and completing ad hoc grant applications;
- A diversified portfolio reduces risk by not having all revenue tied to one funder. This is especially true in a time of reduced federal funding of certain types of research;
- Developing a longer-term sustainability plan including different categories of funding provides the opportunity to develop higher margin financial support. This means that a higher percentage of the funding can be used to invest in future activities beyond basic network expenses.

Because there is a long lead time in developing certain funding relationships, it is important to begin thinking about future potential sources of funding very early in the design phase and regularly as part of the annual strategic planning process. (For more on annual planning, see Module 1: Systems of Leadership.) This can impact the way in which a network might structure participation fees or its research agenda, depending on what opportunities might be included in the strategic plan. It is also important to establish financial metrics and reporting processes as part of the regular network operations such that financial status can be regularly reviewed and ongoing financial health ensured.

Starting the Process for Additional Funding Efforts

Network leadership likely already has significant contacts in multiple areas across the private, public, and commercial funding landscape(s). This is one reason there is so much potential to increase funding through new revenue sources. This guidance is intended to help leadership organize (or re-organize) those assets that may have “resale” value into “product offerings” and to help leadership create a process-driven marketing and sales model.

Each network may have a different mix of funding opportunities related to its “product offering(s),” existing relationships, and best opportunities. While networks need to pursue every opportunity for new sources of funding, network leaders should work to best match various sources of available funding with what the network does and aspires to do.



ASSESSING NETWORK EXPENSES

Revenue opportunities and/or other additional funding sources are just one side of the balance sheet. Experience indicates that expenses also need to be reevaluated on an annual basis. Decisions about investments and expenses made early in a network's development, while serving a purpose at that time, may no longer make sense when more cost-effective options become available later. For example, there is currently an effort underway across all networks to standardize their registry systems by moving to a single common platform. This innovation has the potential to decrease each network's individual registry costs. In addition, new sources of revenue could be reallocated to subsidize participant site fees (see section "Site Participation Fees") or offset travel or other network operational expenses such as the cost of an additional research coordinator or clinical trials training.

Rather than begin by writing a business plan, emerging learning networks often start out by developing a two- or three-year operating budget which allows them to estimate and track expenses over time. This budget is built upon a corresponding detailed work breakdown structure (WBS) containing all tasks and roles/people associated with designing and starting a learning network, then moving it from implementation phase through to annual cycles of sustainable improvement and research work. Typically, an experienced network manager will lead the budgeting/business planning effort and bring in leadership and other stakeholders as needed to provide data and feedback.

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In order to consider long-term financial sustainability from the outset of a network's development, network leadership should look at planned expenses or budget for different phases of the network's development. As mentioned above, it is typical to start with an initial two- to three-year budget that would include the initial phase of design as well as the first year of launching network. However, thought should be given to the next phase of a network's growth as well. This next phase often includes an expansion period, where assumptions can be made about the number of sites that will be added each year and any accompanying expenses (staff, activities, infrastructure, etc.) that will be needed to support the larger network size.

Once the budgeting exercise is complete, some networks may find the development of a formal business plan helpful. The business plan should address the design and implementation phase as well as the first growth cycle. Faculty and physician leads may also find it helpful to incorporate more traditional academic pursuits into the business plan such as plans for grant funding and applications. Network business plans are likely to look very different from one network to another, with some networks not finding them to be important and others relying on them to secure funding.

Resources

- Work breakdown structure template (contact the Learning Networks Program Project Management Group for the latest template, LearningNetworks@cchmc.org)
- Sample Network Business Plan Outline (Appendix 3.1)



NETWORK MODEL

Learning Health System Network Model

GROW COLLABORATIVE NETWORK
Research, Innovation and Improvement Portfolio

Design and Development

One Year Cycles

Design Meeting(s)

Subject matter & application experts
(Patients, Families, Clinicians, Scientists)

Identify Outcomes that Matter

Develop Framework
Select Prototypes and Changes
Prioritize Research
Develop Measurement Strategy
Build Registry

Recruit Participants and Participating Organizations;
Orientation and On-boarding



Network Supports
Monthly webinars, Virtual Meetings, Email, Listserv, Social Media;
Improvement Coaching, Assessments & Monthly Reports

Commons Repository

Data Infrastructure

IMPROVEMENT AND RESEARCH PROJECTS

ANNUAL GOAL AND PRIORITY SETTING

IDENTIFY GAPS IN OUTCOMES

Ongoing Development of Network Infrastructure, Processes and Protocols

- Systems of Leadership —
- Governance and Management —
- Data and Analytics —
- Quality Improvement —
- Community Building and Engagement —
- Science —

ASSESSING REVENUE SOURCES

Each network's leadership is likely aware of a variety of possible funding sources and may have well-developed connections that could serve as sources of new funding. A first step is to perform a stakeholder analysis, cataloguing what a network has to offer each of multiple groups of stakeholders. One approach to this is to review a network's three most recent presentations and the meetings at which these presentations were given. The presentations likely represent the most cutting-edge work or improvements your network has achieved. These advances may present the best opportunity to pursue new revenue streams with the attendees at the meetings where these presentations were made likely being your customers.

For new networks just beginning their work, network achievements may yet to be realized and a different approach should be taken. Consider the return on investment for various stakeholders associated with your network, ranging from potential site partners to industry and other potential supporters. Pitch materials should be developed based on this analysis.

Once an estimate of expenses for the initial several years has been completed, it is critical that each network identify multiple revenue sources to support operations and infrastructure for the network's design, launch, and expansion phases. The financial needs of a network will change during each of these phases, but early planning for how to meet or exceed these needs will enable the best planning and execution.

Several different types of revenue sources are available, and all should be considered as a network is building its financial plan. They each play a different role and have pros and cons to be considered when building a diverse portfolio of potential revenue sources as this provides a network a better chance of achieving long-term financial sustainability. Each type of revenue source is described below.

Resources

- Network Financial Sustainability worksheet (Appendix 3.2)

Grant Funding

Grant funds can be sourced from a wide variety of institutions or even individuals. The key defining element of these funds is that they are provided in response to a specific application process which includes a set of deliverables to which the network is agreeing if chosen as a grant recipient. Grant funds are typically awarded for a set time period and include a requirement of reporting on goals and milestones as laid out in the application.

Private Grants

It is likely that each network has already explored sources for private grants. This is, of course, an important ongoing effort. In pursuing private grant opportunities, a best practice is to review the potential funder's mission statement, strategic plan and existing partners, usually readily available on their website. If a network's mission and objectives match those of a possible funding source, it is more likely a connection will be made that is mutually beneficial for both parties.

For example, InproveCareNow is exploring support opportunities from The Crohn's and Colitis Foundation (CCF). Both share the objective of providing information and training about clinical trials to patients, parents, clinician investigators, and research coordinators. The request to CCF for support for training and education changed to a discussion about collaborative reuse and/or possibly repurposing work already done by CCF. This is an equally valuable asset and establishes a relationship and basis for ongoing discussions about mutually important goals and funding to pursue those goals. It is important in discussions with foundations, and other sources of private grant support, to position your network as a partner with a Foundation, with each bringing value in pursuit of common outcomes. If there is not a genuine alignment in the overarching mission and objectives of your network and that of a potential funder, any possible monies received in a grant mechanism are likely to come with deliverables that are not in line with the ongoing work of the network and may distract from the underlying mission.



Public Grants

Governmental funding bodies such as the NIH and other federal, state and local agencies offer a variety of grant opportunities that may or may not be applicable to and aligned with the objectives of a network. As with private grant mechanisms, each network should engage in regular environmental scans of possible funding sources in the public sector. Particularly in the research domain, publicly sourced grants can be a beneficial source of additional revenue and can support specific efforts of a network.

Site Participation Fees

Site fees are annual fees that each participating improvement team, improvement site, or hospital pays to be a part of the network. Because these are recurring fees, a network can rely on them during their annual budget and strategic planning. Site fees are also tied directly to a network's growth; as the number of sites increase, so too does the corresponding net sum fee total. These fees are therefore instrumental in offsetting the incremental increases in the operational costs associated with expansion.

Commercial Funding

Commercial funding comes from commercial, for-profit customers who are willing to pay the networks for information or access that they find valuable in their work. Examples of this include pharmaceutical or other commercial companies who will pay for network data to be used in drug and device development. There are other opportunities in areas such as repurposing accumulated medical/healthcare data (big data) for reuse in areas such as training and education, research, cost analysis, and healthcare analytics. Softer examples of commercial funding include sponsorship opportunities on behalf of pharmaceutical or device companies in which companies offer networks a set amount of funds in exchange for advertising or sponsorship. Several mature networks receive annual revenue from commercial entities in exchange for allowing them to set up a table at their bi-annual learning sessions. In this case, specific attention needs to be paid to any implications this may have for continuing medical education (CME) credits. This example provides a way to help offset the not-insignificant cost of these events.

Questions often arise as to whether commercial funding dilutes the mission and intent of the network. In response to these concerns, experience recommends that an understanding of how network data will be used and a strategic assessment that this use is in alignment with the network's mission and vision is important. If this assessment yields a favorable answer, commercial funding can be an opportunity to support or accelerate a network's progress and is thus seen as an enabler of, not in opposition to, the network's mission and vision.

Philanthropic Funding

Philanthropic funding is another way in which partnerships with similarly aligned foundations and/or individuals can be forged. One-time donations are a great way to offset the cost of a specific short-term project or enhancement the network is undertaking. These one-time donations can often lead to regular annual support that become a key source of revenue for a network. Alternatively, network alignment with foundation(s) sharing a common patient population or condition can result in long-term financial support of network operations and more integrated approach to supporting the network's population of patients.



APPROACHES TO GRANT FUNDING

Historically, seed funding for new learning networks has come from grants, and as a result, the operating budget equaled the total amount of the grant, plus perhaps some institutional funding (and/or dedicated institutional time for network leaders that may not have been allocated to the learning network's budget but are paid out of hospital overhead.)

Advantages/Disadvantages

Grant funding has a strong advantage for most new networks in that it is familiar to many of their leaders. Grant applications that would support the genesis of a learning network typically follow the same format as other research opportunities that PIs have applied for in the past. The application language and process are well-developed at most host institutions or foundations. In addition, many grants are very clear in their expectations and intent in the request for applications and therefore provide clear guidance on the focus on the application.

Relying on this type of funding, especially from federal government sources, has its disadvantages as well. Most notably, the actual and projected budgets for this type of funding have been declining precipitously in the past several years and therefore, grants are a less reliable source of funding for new research and networks. In addition, there is wide variance in the level of indirect funding associated with these grants. While some are relatively generous, others are relatively limited, and generally none are open to negotiation on this point.

In addition, grant funding has the decided disadvantage that it is timebound, often with relatively short periods of funding. These grants traditionally require significant resource effort and time to complete and often require multiple rounds of applications. As such, it can cause significant distraction and impact available effort for ongoing network improvement and research activities during key application time periods. Nevertheless, grant funding can provide a significant source of financial support, particularly for a nascent network and should not be overlooked.

For networks interested in exploring grant submissions, it helps to provide general background information on the concept and development of the Learning Health System and outcomes achieved to date using the model, as well as a focus on the specific population and aims of the individual network.



APPROACHES TO PHILANTHROPIC FUNDING

Philanthropic funding typically includes funding from a donor foundation or an individual. The key differentiating factor of this funding is that financial support is typically provided with no contractual deliverables or obligation. The funding is made available due to the donor's support of the objectives and stated mission and goals of the network. It is thus made without stipulation to specific terms or deliverables. As such, the key to successful philanthropic funding lies in the identification of potential donors and the ability to communicate the ways in which the network will match with the donor's priorities better than any other opportunities they may be considering.

Consideration of Legal Status

A 501(c) organization is a nonprofit organization in the federal law of the United States according to 26 U.S. Code § 501 and is one of 29 types of nonprofit organizations exempt from some federal income taxes. 501(c)(3) organizations fall into one of three primary categories: public charities, private foundations, and private operating foundations. 501(c)(3) organizations are highly regulated entities. Strict rules apply to both the activities and the governance of these organizations. Networks interested in achieving 501(c)(3) status should consider consulting legal counsel experienced in such matters.

The business planning tools mentioned above may be useful for both 501(c)(3) registered non-profits and networks rooted in a hospital or other location. However, the rules and restrictions on how funds are budgeted, how revenue is recognized, and how (or if) funds may be saved or carried over from year to year vary significantly between the two. To give themselves more financial flexibility and control in their long-term business planning, a few more mature learning networks have opted to register their networks as 501(c)(3) corporations, yet they choose to remain dependent on their original host hospitals for operational and leadership support. Depending on the condition of focus and genesis of the network, it can be difficult to find administrative and clinical staff experienced in network operations and management outside of the hospital setting.

Identifying Prospective Foundations or Donors

Potential donors can include very targeted prospects (e.g., grateful patients, condition-specific foundations) as well as organizations or individuals who understand and support the conceptual model and impact of your network. Appeals to some of the broader foundations could be strengthened by approaching conversations jointly with other network efforts. Key questions to consider when identifying and approaching these foundations or donors are:

- What is their stated vision, mission or purpose?
 - How well does it align with that of your network?
- What have they funded in the past?
- What appears to be most compelling to them?
 - How can you structure your request to best match this?
 - How well does your network effort fit with these priorities?



APPROACHES TO COMMERCIAL FUNDING

The following section lays out a basic approach for learning health system network leadership to pursue revenue opportunities in the areas of drug and device development, as well as in repurposing accumulated medical/healthcare data (big data) for reuse in areas such as training and education, cost analysis, and healthcare analytics.

A value proposition is an innovation, service, or feature that makes a company or product valuable to customers. One value proposition for commercial companies to work with learning health systems and patient communities (networks)—especially those driven by quality improvement and coproduction—is the quality, volume (either breadth or depth), completeness, and reusability of data and collaboration by patients, parents, and care teams that makes a better clinical trials network.

In clinical trials, time equals money to commercial funders. It is important that all study sites in a trial complete IRB and contract processes as quickly as possible. Six months is good. Ninety days is valuable. Learning health systems offer the advantage of an infrastructure that supports rapid completion of such requirements. The other opportunity for networks in clinical trials is to enroll 100% of required research subjects in half the time allotted by contract, which again learning health systems are uniquely positioned to accomplish. These abilities are worth premium pricing agreements and are unique selling points available to learning health systems.

For all types of commercial funding, it is important to pursue a variety of opportunities early so there are no gaps in the investment required to support community growth and development. Commercial sales cycles in these markets can require six to nine months. Before that cycle even begins, a business development expert will require about three months with a budget to build the “product package” and implement a marketing and sales plan. In summary, the process of confirming an engagement with a commercial funder takes time and should thus be considered as part of a long-term planning process for future sources of funding.

Building the Product Package

The first step to determine sources available for commercial funding opportunities is to inventory what “product(s)” —in the broad sense of the word—a network has that may be of interest to commercial organizations. This funding comes from commercial, for-profit customers who are willing to pay the networks for information or access to what they find valuable in their work.

The most obvious is data. Solutions for Patient Safety, for example, has a trove of hospital safety information that likely can be repackaged for sale. And realize that a network—while it may not have a large volume of data—has “big” data, nonetheless. The opportunities to monetize that data in continuing medical education and training, or deeper data analytics, is very real and a good potential revenue source. Similarly, clinical trials can be an excellent source of alternative revenues.

A best practice for re-selling data is to provide customers with a catalogue of data elements available. From that description, engage the client to coproduce a data query. Run that query internally and provide a quality-approved draft report for client review. It is important to be clear with all clients that you are not selling access to your registry, you are selling coproduced query results.



Things to keep in mind when building the product package include:

Inventory of Assets

The best way to determine what a “product package” will include is to do an inventory of assets. Data, patient community, membership numbers, disease expertise (research and publications), and clinical trials likely present the best opportunities to generate commercial revenue. Being able to run a data query across a network (registry) will bring value in multiple ways. To determine potential for success in marketing/selling your selected product(s), it is a worthwhile exercise to do a SWOT analysis, which involves identifying strengths, weaknesses, opportunities and threats your product(s) will face in the commercial marketplace.

Make it easy for customers to evaluate your product

Sales process time, particularly with new clients, can be saved if there is a set of supportive and condensed documentation This includes but may not be limited to:

- Network website
- A one-pager description of the product(s)
- Curricula Vitae
- Process flow
- Capabilities presentation
- Brochure

Marketing and Sales

Marketing and Brand

A network’s brand has the potential to become its most valuable asset. Presentations and publications, catalogued as a part of the product “package,” can be used to explore commercial opportunities most likely to succeed by matching expertise to markets and companies most in need of your “product.” For example, Solutions for Patient Safety (SPS) might find immediate opportunity for developing and charging for patient safety CME-approved training modules. This could generate revenue, further build an international brand, increase membership, and further the mission. ImproveCareNow (ICN) agreed to a contract with a pharma company to do a pediatric inflammatory bowel disease (IBD) study using more than 20 study sites in the ICN network. With the collaboration and cooperation within the ICN Community, patients and clinicians are motivated by advancing the network to continue to improve outcomes for children with IBD. Those involved in the trial anticipate that this network-based approach will allow for faster and better execution and study and could prove transformational in the world of clinical trials. Performing this clinical trial faster and better, will make this model transformational for clinical trials.

Sales Approach

Each clinician or healthcare professional in every network likely already has a list of contacts in the commercial companies related to the network. A business development professional can organize those contacts with network leadership to generate a list of best prospects. Such a list could shorten the sales cycle. The business development professional can then work with each leadership individual to schedule presentations. The business development professional must be sufficiently skilled to handle contract negotiations. This is a process that will require legal support and it behooves every network to develop a community agreement to streamline the contract process.

In clinical trials, an excellent way to build a pipeline is to compare network clinical expertise to clinical trials listed in www.clinicaltrials.gov. This gives a rapid analysis of what companies are most involved in clinical trials related to your network.



Contracts

Commercial contracts often include several separate documents/agreements. These documents include but may not be limited to:

- Confidentiality, also known as Non-Disclosure Agreements
- Financial Disclosure
- Data Privacy Practices
- Regulatory documentation (in clinical trials)
- 1572, Informed Consent, IRB, DUA, BAA etc.
- Master Services Agreement (MSA)
- Statement of Work (SoW)
- Project budget

Speed of execution is important in this environment. A pricing model should be built so preparing budgets is easier and the management and leaderships team are able to be nimbler in their responses. If possible, it is also good business process to ask a contract attorney with intellectual property (IP) experience to review the documents and assist with negotiations.

Again, to be valuable enough to obtain premium pricing for services, the contract process must be streamlined.

Early Adopters

In the sales and marketing book “Crossing the Chasm,” the authors describe a certain subset of decision makers called early adopters who will take a risk on a new “product,” but most will not. (Moore, 2014) One strategy that builds on this concept is to give those early adopters some sort of preferred access and adapt your offerings to feedback and input, when valuable. Creating an advisory board or partnering with early adopters, in both the commercial healthcare and clinical trials marketplaces, is popular and may extend opportunities within those partner companies for new revenue streams. Be cautious not to let sales opportunities that require too much additional effort distract network business development professionals or leadership.

Value Proposition

Networks should understand and articulate their value proposition to member sites/centers and potential funders/sponsors. Those value propositions result from, but are not necessarily the same as, the discrete products, programs, or services provided by the network, which in turn should be supported by key people/role players in the network, and adequate funding and other resources to sustain them. Understanding this value proposition can help a network decide how to approach each of the different types of funders.

In the “Systems of Leadership” component of the Network Maturity Model, ‘Demonstrating the Network’s Value,’ reminds us of the distinction between a network’s value proposition and the actual cost of providing its products/services. As an example, one service a network provides to member sites may be quality improvement (QI) coaching. A network likely chooses not to itemize the cost of QI coaching when it issues an invoice for each site’s annual participation fee. QI coaching entails a cost that must be borne by network members, but the dollar value of that QI coaching to those network sites may far exceed the actual cost. Those coaching services may allow sites to reduce emergency department visits, hospital readmissions, hospital stays, serious safety events, or medical errors thanks to network-sponsored QI efforts; they may recoup their “investment” in the network many times over. Ideally, this is the kind of value proposition that network leaders offer members, year after year.

Resources

- Improving Renal Outcomes Collaborative (IROC) Value for Administrators (see Module 1: Systems of Leadership Appendix 1.11)





Identifying Market Opportunities and Threats

A network may wish to consider pursuing new activities, for example, industry-funded research studies. The related expenses and revenues of such activities should be understood. The competitors in those markets should be understood—their advantages, disadvantages, current customers, geographical reach, etc.—and preferably listed by name.

Alternatively, learning networks, as non-profit organizations whose overall mission is to improve the lives of patients and families, may wish to pursue activities for which there is not an apparent market or customer yet, or perhaps never will be. Obviously, to ensure the network's continued viability, its business plan should achieve a net balance where revenue-generating activities equal or preferably exceed non-revenue-generating activities.

In addition, networks should understand how certain external factors could threaten their delivery of existing products or services, or their planned delivery of new products or services. For example, a change in federal legislation, or a drastic reduction in the budget of a key federal agency, could be a threat to a network. Network managers should consider contingency plans if such threats materialize, such as diversifying their sources of funding, maintaining savings in a bank account, or developing a scaled-back, lower-cost operating plan.

DEVELOPING A NETWORK PRO FORMA MODEL

Development of a Financial Plan

The financial plan of a network or a non-profit is not significantly different than any other financial plan. It should include a pro forma income statement with projected revenues and expenses resulting in expected net income for the financial year.

At a higher level of sophistication, a network could perform financial scenario and/or sensitivity analysis. Financial scenario analysis describes the projected net income for a network resulting from a particular market scenario. In sensitivity analysis, variables affecting a certain financial outcome (such as revenue) are isolated and their cause-effect relationship is calculated or estimated; the effect of changes in these variables are modeled in terms of what-if statements and then the results are described in respective income statements. The point of both types of analysis is to estimate in quantitative/dollar terms the potential effect of operating risks and market opportunities and threats. These two types of analysis allow network managers and leaders to assess the network's resilience to market "shocks," or its ability to pursue new opportunities without overextending itself financially.

The financial plan may also include a balance sheet or statement of financial position (SOP). The SOP lists the network's Assets (usually cash), Liabilities (debts) and resulting Net Assets, which is equivalent to the net worth of the organization. An SOP is only relevant if the network carries over or saves significant assets from one financial year to the next. As mentioned above, most networks do not carry over significant funding; and if they do, it is already earmarked for specific activities in the following financial year. Instead, networks may opt to develop multi-year income statements, then track actual annual expenses and revenue vs. their projections.

Leaders should not expend effort developing the business plan themselves, but rather provide guidance and oversight to the business planning team/network management group, and give the business plan their final approval. Depending on the network's organizational structure, network managers should present the business plan to other appropriate stakeholder groups as well.

Resources

- Pro forma template (Appendix 3.3)



YOUR IMPROVEMENT SUGGESTIONS

We strive to provide the best guide and resources for you. How did we do?

Your feedback helps us continuously improve. Please share your feedback with us:
<https://www.surveymonkey.com/r/ZHGJF88>. Thank you!

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